

Response

Claims 1 and 3-15 of the subject application are pending. Applicant has amended claims 1, 3-9, 11-15. Applicant has canceled claim 6 and has not added any claims. Accordingly, claims 1, 3-5, and 7-15 are presently being examined.

Support for the Amendments

Applicant has amended claim 1 in order to more clearly describe and distinctly claim the subject matter of applicant's sugar-free soft chew tablet composition. Specifically, applicant has canceled claim 6 and incorporated certain of the emulsifiers of claim 6 into claim 1. Applicants have entered this amendment in order to overcome the Examiner's rejections. Applicant has amended the remainder of the claims to correct certain clerical and typographical errors. These amendments to the claims are fully supported in the specification as originally filed, and thus no new matter is introduced by these amendments in accordance with 35 U.S.C. §132. Accordingly, applicant requests entry of these amendments.

Species Requirement

The Examiner states that in the paper dated January 29, 2003, applicant elected with traverse hydrogenated starch hydrolysates and lactitol for species A, partially hydrogenated soybean oil for species B, lecithin for species C, dietary fibers for species D, carrageenan for species E, hydroxypropylmethyl cellulose for species F, and psyllium for species G.

Withdrawal of Rejections of Office action of July 25, 2006

The Examiner states that the finality of the Office action of July 25, 2006 is hereby withdrawn and new rejections are presented herein.

Claim Objections

The Examiner has objected to claim 1 on the basis of the following informalities: the claim lists ingredients a), b) and d) but skips the use of c) to refer to an ingredient. In addition, the Examiner in line 7, the phrase "has be cooled" should correctly be "has been cooled." Applicant's amendments to claim 1 obviate the Examiner's objections..

Rejection of Claims 1 and 3-15 under 35 U.S.C. §102(b) as being anticipated by *Bunick et al.*

The Examiner has rejected claims 1 and 3-15 under 35 U.S.C. §102(b) as being anticipated by United States pat. no. 4,714,620 (*Bunick et al.*). The Examiner states that *Bunick et al.* teaches a soft, sugar free, chewable composition containing 35% to 89% hydrogenated starch hydrolysates, 1% to 10% cellulose, 0.1 to 7.5% whipping agent, 2% to 10% fat, and 7% to 12% water (see claim 1). The Examiner states that the whipping agent is soy protein (see claim 4) and soy proteins naturally contain lecithin. The Examiner states that the fat is claimed as partially hydrogenated oils including soy oil (see claim 5). The Examiner also states that the composition also contains up to 45% lactitol and/or maltitol (see claim 10). The Examiner states that the cellulose are fibers and include hydroxypropylmethylcellulose (see claim 2). The Examiner states that the composition also contains up to 5.5% of a thickening agent, which is psyllium and/or carrageenan (see claim 7). The Examiner states that *Bunick et al.* teaches that the composition can be shaped into any desirable form including a tabloid shape (see claim 8, lines 42-45) and that "tabloid" is a type of tablet. *Bunick et al.* specifically claims a composition that contains all of the same ingredients as claimed by applicant in the same amounts as claimed by applicant. The Examiner states that *Bunick et al.* does not specifically teach that the composition is reheatable, however, since the reference teaches using the same ingredients as claimed in the same amounts as claimed, the *Bunick et al.* composition would be reheatable. Applicant's claims as amended obviate the Examiner's rejections.

The *Bunick et al.* reference discloses a sugarless chewable aerated confectionery composition which comprises a hydrogenated starch hydrolysate in an amount of about 35% to about 89%, cellulose in an amount of about 1% to about 10% wherein the cellulose is a non-water soluble and a water-soluble cellulose such that the ratio of water-soluble to non-water soluble cellulose is about 1:3 to about 3:1, a whipping agent in an amount of about 0.1% to about 7.5%, fat in an amount of about 2% to about 10%, and a final water content of about 7% to about 12%. (*Bunick et al.* at claim 1).

Bunick et al. states that "[n]ougats are perhaps the most complex and difficult of the generic confectionery bases to prepare. They are aerated confections whose density largely depends on a frappe element and texture on a syrup element along with its subsequent crystallization. The preparation of soft confections such as nougat, involves the combination of two primary components thereof, namely a high boiling syrup such as corn syrup or the like, and a relatively light textured frappe, generally prepared from gelatin, egg albumen, milk proteins such as casein, and vegetable proteins such as soy protein, and the like." *Bunick et al.* at col. 1, lines 6-17.

Applicant's invention provides a sugar-free soft chew tablet composition comprising a reheatable composition that includes a) a mixture of two polyols present in an amount from about 15% to about 80%, by weight, the polyols being selected from the group consisting of hydrogenated starch hydrolysates, maltitol, lactitol, and mixtures thereof; b) an emulsifier system present in an amount from about 1.0% to about 30%, by weight, wherein the emulsifier is selected from the group consisting of acetylated mono glycerides, glycerol esters, glycerol monostearate, polyglycerol esters, propylene glycol esters, sorbitan esters, polysorbate esters, sodium laurel sulfate, polyethylene glycols, sorbitol mono-, di- and tri-stearates and mixtures thereof; c) water in an amount up to about 15% by weight; and d) an active agent in an amount from about 0.1% to about 70%, by weight, that is added to the reheatable composition either upon cooling or after the composition has been cooled and later reheated to form the soft chew tablet composition. (Applicant's specification at claim 1)

The *Bunick et al.* reference does not anticipate applicant's claims because *Bunick et al.* does not disclose the use of applicant's emulsifiers (component (b)). As set out above, applicant's emulsifiers are selected from the group consisting of acetylated mono glycerides,

glycerol esters, glycerol monostearate, polyglycerol esters, propylene glycol esters, sorbitan esters, polysorbate esters, sodium laurel sulfate, polyethylene glycols, sorbitol mono-, di- and tri-stearates and mixtures thereof. In addition, the Examiner admits that *Bunick et al.* does not specifically teach adding the ingredients in all of the amounts claimed by applicant.

Accordingly, the Examiner's rejection of claims 1 and 3-15 under 35 U.S.C. §102(b) as being anticipated by *Bunick et al.* should be withdrawn.

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

Rejection of Claims 1 and 3-15 under 35 U.S.C. §103(a) as being unpatentable over *Bunick et al.*

The Examiner has rejected claims 1 and 3-15 under 35 U.S.C. §103(a) as being unpatentable over *Bunick et al.* The Examiner admits that *Bunick et al.* does not specifically teach adding the ingredients in all of the amounts claimed by applicant but argues that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. The Examiner argues that optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ and it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Applicant's claims as amended obviate the Examiner's rejections.

The *Bunick et al.* reference does render applicant's claims obvious because *Bunick et al.* does not disclose the use of applicant's emulsifiers (component (b)). As set out above, applicant's emulsifiers are selected from the group consisting of acetylated mono glycerides, glycerol esters, glycerol monostearate, polyglycerol esters, propylene glycol esters, sorbitan esters, polysorbate esters, sodium laurel sulfate, polyethylene glycols, sorbitol mono-, di- and tri-stearates and mixtures thereof. In addition, the Examiner admits that *Bunick et al.* does not specifically teach adding the ingredients in all of the amounts claimed by applicant.

Moreover, the Examiner attempts to equate the whipping agent of *Bunick et al.* with applicant's emulsifier. *Bunick et al.* states that "[t]he whipping agent functions as a means of holding air introduced into the product to produce a uniform dispersity of air cells within the confection leading to a lower specific gravity and considerable modification to the texture." *Bunick et al.* at col.4, lines 30-34. Emulsifiers are surface active agents (surfactants) which are compounds that reduce surface tension when dissolved in aqueous solutions or which reduce interfacial tension between two liquids, or between a liquid and a solid. (Condensed Chemical Dictionary, 8th Edition, Gessner Hawley, Van Nostrand Reinhold Company, p. 840, copy enclosed.

In addition, *Bunick et al.* incorporates cellulosics and states that "it is believed that incorporation of the cellulosics reduce the inherent excessive cold flow and stickiness associated with hydrogenated starch hydrolysate confection by occupying surface space, building body to the final piece and sorbing moisture." *Bunick et al.* at col.3, lines 19-23. This is not applicant's sugar-free soft chew tablet composition in which an active agent may be added to the reheatable composition either upon cooling or after the composition has been cooled and later reheated to form the soft chew tablet composition. (Applicant's claim 1)

Accordingly, the Examiner's rejection of claims 1 and 3-15 under 35 U.S.C. §103(a) as being unpatentable over *Bunick et al.* should be withdrawn.

Obviousness of a composition or process must be predicated on something more than it would be obvious "to try" the particular component recited in the claims or the possibility it will be considered in the future, having been neglected in the past. *Ex parte Argabright et al.* (POBA 1967) 161 U.S.P.Q. 703. There is usually an element of "obvious to try" in any research endeavor, since such research is not undertaken with complete blindness but with some semblance of a chance of success. "Obvious to try" is not a valid test of patentability. *In re Mercier* (CCPA 1975) 515 F2d 1161, 185 U.S.P.Q. 774; *Hybritech Inc. v. Monoclonal Antibodies. Inc.* (CAFC 1986) 802 F2d 1367, 231 U.S.P.Q. 81; *Ex parte Old* (BPAI 1985) 229 U.S.P.Q. 196; *In re Geiger* (CAFC 1987) 815 F2d 686, 2 U.S.P.Q.2d 1276. *In re Dow Chemical Co.* (CAFC 1988) F2d, 5 U.S.P.Q.2d 1529. Patentability determinations based on that as a test are contrary to statute. *In re Antonie* (CCPA 1977) 559 F2d 618, 195 U.S.P.Q. 6; *In re Goodwin et al.* (CCPA 1978) 576 F2d 375, 198 U.S.P.Q. 1; *In re Tomlinson et al.*

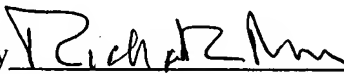
(CCPA 1966) 363 F2d 928, 150 U.S.P.Q. 623. A rejection based on the opinion of the Examiner that it would be "obvious to try the chemical used in the claimed process which imparted novelty to the process does not meet the requirement of the statute (35 U.S.C. 103) that the issue of obviousness be based on the subject matter as a whole. *In re Dien* (CCPA 1967) 371 F2d 886, 152 U.S.P.Q. 550; *In re Wiaains* (CCPA 1968) 397 F2d 356, 158 U.S.P.Q. 199; *In re Yates* (CCPA 1981) 663 F2d 1054, 211 U.S.P.Q. 1149. Arguing that mere routine experimentation was involved overlooks the second sentence of 35 USC 103. *In re Saether* (CCPA 1974) 492 F2d 849, 181 U.S.P.Q. 36. The issue is whether the experimentation is within the teachings of the prior art. *In re Waymouth et al.* (CCPA 1974) 499 F2d 1273, 182 U.S.P.Q. 290. The fact that the prior art does not lead one skilled in the art to expect the process used to produce the claimed product would fail does not establish obviousness. *In re Dow Chem. Co.* (CAFC 1988) 5 U.S.P.Q.2d 1529.

The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggest to one of ordinary skill in the art. The references of record fail to teach or suggest applicant's invention as a whole.

S. Rao Cherukuri
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In view of the foregoing Amendment and Response, applicants request reconsideration pursuant to 37 C.F.R. §112 and allowance of the claims pending in this application. Applicant requests the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments, which might be most expeditiously handled by a telephone conference. No fee is deemed necessary in connection with the filing of this Amendment and Response. If any fee is required, however, authorization is hereby given to charge the amount of such fee to Deposit Account No. 13-4822.

Respectfully submitted,
S. Rao Cherukuri

By 
Richard R. Muccino
Reg. No. 32,538
Attorney for Applicant(s)

Direct communications to:
Richard R. Muccino
758 Springfield Avenue
Summit, New Jersey 07901
voice (908) 273-4988
fax (908) 273-4679

The
Condensed Chemical
Dictionary

EIGHTH EDITION

Revised by

GESSNER G. HAWLEY

Formerly Executive Editor, Reinhold Publishing Corporation
Coeditor, Encyclopedia of Chemistry



VAN NOSTRAND REINHOLD COMPANY
New York Cincinnati Toronto London Melbourne

"Superinone."¹⁶² Trademark for tyloxapol (q.v.).

"Superlith."²²³ Trademark for imported zinc sulfide pigments.

Grades: Available as pure zinc sulfide, 60% zinc sulfide.

"Superloid."²²² Trademark for ammonium alginate, a hydrophilic colloid.

Uses: Suspending, thickening, emulsifying and stabilizing agent in creaming and bodying of rubber latex products; protective colloid in resin emulsion paints; adhesives; fire-retarding compositions; ceramics, etc.

"Superlose."²⁵³ Trademark for amylose fraction of potato starch.

"Superlume."²⁸⁸ Trademark for a super-leveling bright nickel electroplating process on steel stampings, brass, copper, zinc die castings, etc. The materials used are nickel sulfate, nickel chloride, boric acid and addition agents.

supernatant. A liquid or fluid forming a layer on the surface of a solid or another liquid.

superoxide. A compound characterized by the presence in its structure of the O_2^- ion. The O_2^- ion has an odd number of electrons (13) and, as a result, all superoxide compounds are paramagnetic. At room temperature they have a yellowish color. At low temperature many of them undergo reversible phase transitions accompanied by a color change to white. The stable superoxides are:

Sodium superoxide	NaO_2
Potassium superoxide	KO_2
Rubidium superoxide	RbO_2
Cesium superoxide	CsO_2
Calcium superoxide	$Ca(O_2)_2$
Strontium superoxide	$Sr(O_2)_2$
Barium superoxide	$Ba(O_2)_2$
Tetramethylammonium superoxide	$(CH_3)_4NO_2$

In these compounds each oxygen atom has an oxidation number of $-\frac{1}{2}$ instead of -2 , as a normal oxide.

"Supernilla."³⁴² Trademark for natural vanilla concentrate in liquid form.

"Superoxol."¹²³ Trademark for hydrogen peroxide (q.v.).

"Superpax."³³⁷ Trademark for 92 to 94.5% zirconium silicate with bulk density 68 lbs/cu ft; average particle size 5 microns max. Used in ceramic glazes and as a filler for resins and rubbers.

superphosphate (acid phosphate). The most important phosphorus fertilizer, made by the action of sulfuric acid on insoluble phosphate rock (essentially calcium phosphate, tribasic) to form a mixture of gypsum and calcium phosphate, monobasic. A typical composition is $CaH_4(PO_4)_2 \cdot H_2O$ 30%; $CaHPO_4$ 10%; $CaSO_4$ 45%; iron oxide, alumina, silica 10%; water 5%.

Typical analysis: Moisture 10-15%; available phosphoric acid (as P_2O_5) 18-21%; insoluble phosphoric acid 0.3-2%; total phosphoric acid (as P_2O_5) 19-23%.

Grades: Based on available P_2O_5 . Containers: Bags; bulk; multiwall paper sacks; carloads.

Use: Fertilizer.

See also triple superphosphate and nitrophosphate.

superphosphoric acid. See polyphosphoric acid.

"Supersheen."²⁹² Trademark for caustic soda solution containing chelating agent and wetting agent. Containers: Tank cars and tank trucks.

Hazard: Highly toxic and strong irritant to skin and tissue.

Uses: Bottle washing and food plant sanitation.

"Supersil."⁴³⁶ Trademark for ground silica. Available in standard grades from 100 to 325 mesh.

Uses: Manufacture of ceramics, porcelain enamel, scouring powders and buffing compounds, fiber glass, autoclave concrete products, chemicals, asbestos products and for cementing deep oil wells.

"Supersilicate."²⁴⁴ Trademark for a compound consisting essentially of the formula, $1.5 Na_2O \cdot SiO_2 \cdot 5.5 H_2O$.

Uses: Laundry and metal cleaning; paint remover; concrete floor cleaner; base for cleaning compounds.

"Supersize."⁵⁵³ Trademark for hydroxyethyl corn starches.

"Super-sol."²⁵ Trademark for an odorless petroleum naphtha; a rapid-drying highly purified solvent.

Uses: Carrier for insecticides; preparation of odorless paints; cleaning compositions.

"Super Spectra."¹³³ Trademark for an impingement carbon black used for jet black enamel and lacquers requiring satin finish. Containers 6 1/4-lb bags.

"Super Stod-Sol."²⁰⁰ Trademark for a petroleum solvent.

Properties: Water-white; boiling range 310-353°F; sp. gr. 0.779 (60°F); wt/gal 6.49 lbs (60°F); flash point 102°F.

Containers: Drums, tank wagon, tank cars.

Hazard: Flammable, moderate fire risk.

Uses: Dry-cleaning solvent.

See also Stoddard Solvent.

"Supralan."³⁰⁷ Trademark for metallized acid colors of good fastness and level dyeing properties.

"Supramine" XA.³⁰⁷ Trademark for a leather chemical, solubilized sulfur phenol condensate; 75% active.

"Supranol."³⁰⁷ Trademark for dyestuffs used on wool and silk. Good fastness to light, washing, and sea water. Can also be used on leather.

"Suprarenin."¹⁶² Trademark for synthetic epinephrine.

"Suprex."²⁸⁵ Trademark for a group of clays (sedimentary kaolins) from South Carolina.

Uses: Reinforcing agent in rubber products; (produces high modulus and tensile, good abrasion resistance and a stiff uncured mixture); carrier in pesticides where its fine particle size, plate-like shape and good wetting provide high adsorption in concentrates and excellent suspension behavior in wettable powders.

"Surfacaine."¹⁰⁰ Trademark for cyclomethycaine (q.v.).

surface active agent (surfactant). Any compound that reduces surface tension (q.v.) when dissolved in water or water solutions, or which reduces interfacial tension between two liquids, or between a liquid and a solid. There are three categories of surface-active agents: detergents, wetting agents, and emulsifiers; all have the same basic chemical mechanism and differ chiefly in the nature of the surfaces involved. For further information see under these three entries; also see interface; surface chemistry.

surface chemistry. The observation and measurement of forces acting at the surfaces of gases, liquids, and solids or at the interfaces between them. This in-

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